DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 8, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Reference: Warning Letter SEA 02-25
Inspection ID: 1514640007

Horacio Gutierrez, M.D., Radiologist
Mason General Hospital
901 Mountain View Drive, Bldg 1
P.O. Box 1668
Shelton, Washington 98584

WARNING LETTER

Dear Dr. Gutierrez:

We are writing to you because on December 27, 2001, your facility was inspected by a representative of the State of Washington, Mark Radonich, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

1. Phantom QC records were missing for at least 4 weeks for unit 2, Bennett X-Ray Corp.

2. Processor QC records for the month of July 2001, were missing for at least 30% of operating days, for processor 1, Kodak, RP X-OMAT M6B,6AN,6AW.

3. Processor QC records were missing at least 5 consecutive days for processor 1, Kodak, RP X-OMAT M6B,6AN,6AW.

4. There was no documentation verifying that the interpreting physician, [redacted] met the initial requirement of holding a valid state license to practice medicine.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings were:

1. Corrective action before further exams was not documented for unit 2, Bennett X-Ray Corp., for a failing image score, or for a phantom background optical density, or for density difference outside the allowable regulatory limits.

2. Mammograms were processed in processor 1, Kodak, RP X-OMAT M6B,6AN,6AW, when it was out of limits on at least 2 but less than 5 days.

3. There was no documentation verifying that the following interpreting physicians have met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months: [redacted] (12.7 CME's in 36 months); [redacted] (0 CME's in 36 months); [redacted] (13 CME's in 36 months); [redacted] (9 CME's in 36 months).

4. There was no documentation verifying that the radiologic technologist, [redacted], met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months (0 CEU's in 36 months).

5. There was no documentation verifying that radiologic technologists [redacted] met the continuing experience requirement of each having performed 200 mammography examinations during the 24 months preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

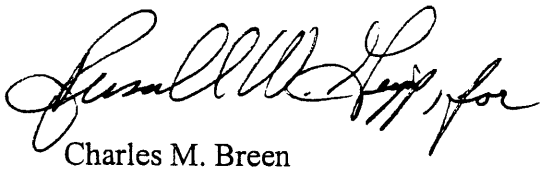
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: patient names or identification should be deleted from any copies submitted).*

Please submit your response to U.S. Food & Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law.

You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

Sincerely,



Charles M. Breen
District Director

*This note is not applicable for letters that also address patient notification.

CC:
Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
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Reston, Virginia 20191

Mark Radonich
State of Washington
Division of Radiation Protection
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